REMARKS/ARGUMENTS

Claims 1-6, 10, 14, 15, 18-20, 22 and 23 have been amended and claims 81-85 have been cancelled from the application. Claims 29-80 were previously cancelled. Claims 1-12 and 14-28 are pending in the application.

Claim Rejections under USC 35 102(b)

The Examiner has rejected claims 1-9, 13-14, 21, 24-28, 81, 83 and 84 under 35 USC 102(b) as being anticipated by the teachings of Stiene (WO 02/49507). Applicant respectfully submits that the amended claims submitted herewith define subject matter clearly distinguished from Stiene.

Amended claims 1 and 3 now clearly define subject matter not taught in Stiene.

The invention is directed to an injector fluid pump using an injector fluid for pushing a separate sample fluid along a sample fluid flow path of a sample fluid analysis device. The injector fluid is separate and distinct from the sample fluid. An injector fluid of a preselected electrolyte concentration is used as compared to a sample fluid of unknown composition, for example fluid collected from a patient. Using an injector fluid of known composition allows for an exact control of the pressure generated by the pump and, therefore, the pumping pressure applied onto the sample fluid. Of course, electro-osmotic pumping of the injector fluid of known composition rather than the sample fluid of unknown composition not only allows for a more exact and predictable control of the pumping conditions, but also avoids any potential detrimental effect on the sample and its components by the electric field applied for pumping. The independent claims now clearly differentiate throughout between the injector fluid and a sample fluid. The claims further distinguish between a sample fluid containing sample fluid flow path in the sample analysis device and an injector fluid flow path including the closed reservoir, the valve for opening the reservoir and the effluent end for connecting the injector fluid flow path to the sample flow path. The injector fluid flow path further includes the isolator to prevent passive flow of injector fluid contained in the injector fluid flow path past the effluent end after opening of the valve. Moreover, the injector fluid flow path includes a driving structure for electro-osmotically pumping the injector fluid in the injector fluid flow path across the isolator and into the sample fluid containing sample fluid flow path, to hydraulically push

the sample fluid along the sample fluid flow path. Furthermore, the reservoir is defined as an integral reservoir, which is initially closed. A valve is recited in the independent claims, which valve allows for the selective opening of the initially closed reservoir.

Stiene neither teaches nor suggests an injector pump for pushing a sample fluid in a downstream sample fluid analysis device by way of an injector fluid of known composition. In contrast, Stiene discloses a sample collection and analysis device. Pumping of the sample fluid is possible, but only by pumping the sample fluid itself. The use of an injector fluid separate and distinct from the sample fluid is neither disclosed nor suggested. Stiene also neither teaches nor discloses an initially closed injector fluid reservoir integral to the pump or a valve for the selective opening of the reservoir and the release of the injector fluid from the reservoir into the injector fluid flow path. Thus, Stiene neither discloses nor suggests a pump including an integral, initially closed, injector fluid filled reservoir and a valve for selectively releasing the fluid from the reservoir. Stiene also fails to disclose separate injector fluid and sample fluid flow paths, whereby the injector fluid flow path is connected to the integral injector fluid reservoir.

The principle of the injector pump of the invention is to electro-osmotically pump an integral injector fluid of known consistency to generate a head pressure for the downstream pumping of another, distinct sample fluid in the sample analysis device. The integral injector fluid, or pump priming fluid, is used as a hydraulic pushing fluid for the pumping of other fluids in the downstream device. This allows, for example, for the pumping of a sample fluid without having to expose the sample fluid to an electrical potential, which may be disadvantageous. The use of an upstream injector pump with integrated pushing or priming fluid also overcomes the problems inherent with the electro-osmotic pumping of physiological fluids. As will be appreciated by the skilled person, the direct eletro-osmotic pumping of physiological fluids may require the use of high voltages, which could result in damage to components in the sample fluid. Moreover, the voltage needed for pumping physiological fluids depends on the ionic strength of the fluid, which will of course vary from sample to sample. By using an upstream injector pump with an integrated priming fluid of known consistency, the embodiments of the present application are able to hydraulically pump downstream liquids of completely unknown consistency and completely avoid the need to expose a sample fluid to an electrical potential. This is clearly neither taught nor even suggested in Stiene. Thus, the

amended claims are distinguished from the cited reference and believed acceptable under USC 35 102(b). Favorable consideration of the amended claims is respectfully requested.

Stiene discloses a sample fluid (blood) collection and analysis device. Stiene makes no mention whatsoever of any injector fluid separate from a sample fluid to be analyzed. All fluids collected in and pumped within the apparatus of Stiene are sample fluids to be analyzed, which means fluids of unknown composition, and not injector fluids of known composition.

It is the Examiner's position that Stiene teaches an integral reservoir connected to a fluid flow path with an effluent end, an isolator to prevent passive flow of the fluid from the effluent end and a pair of electrodes for pumping the fluid across the isolator. Applicant respectfully points out that the reservoir identified by the Examiner is a sample collection reservoir which is an open, initially empty sample reservoir, not an initially closed injector fluid filled reservoir. The lancet of the Stiene device, when filled, includes a sample of unknown composition, rather than an injector fluid of a preselected electrolyte compostition. Applicant further points out that the device of Stiene is not constructed with separate injector fluid and sample fluid flow paths. All flow paths in Stiene are sample fluid flow paths. Also, in the Stiene device, the only manner of displacing the sample fluid is to pump the sample fluid itself, not a separate injector fluid of known composition. Moreover, in the Stiene device, the only way of getting sample fluid into that portion of the sample fluid flow path located on the other side of the isolator is to pump sample fluid across the isolator. That means all the sample to be analyzed is subjected to the high voltages required to pump physiological fluids, thereby potentially damaging components in the sample which are sensitive to electrical fields. The completely opposite approach of pumping a separate injector fluid of known composition rather than the sample fluid, in order to facilitate control of the pumping conditions and avoid damage of sensitive sample components, and to use the pumped injector fluid as a hydraulic pushing fluid for the sample is neither disclosed in Stiene nor even possible with the Stiene device.

In summary, Stiene neither discloses nor suggests a pump for pushing an injection fluid into a fluid sample containing sample fluid flow path of a fluid sample analysis device. Stiene furthermore fails to teach an injector pump which includes an integral, injector fluid reservoir and a valve for selectively releasing the fluid from the reservoir. Moreover, Stiene fails to disclose a pump wherein the injector fluid released from the integral reservoir by way of the

valve is released into a micorporous fluidic path fluidically separated from the fluid sample flow path of the analysis device by an isolator to maintain the injector fluid in the fluidic path until it is electro-osmotically pumped across the isolator to hydraulically advance a sample in the sample fluid flow path. Therefore, Stiene cannot anticipate the subject matter of the claims as amended and withdrawal of the Examiner's rejection under USC 35 102(b) is respectfully requested.

Claim Rejections under USC 35 §103(a)

The Examiner has rejected claims 10-12, 15-20, 22-23 and 82 under 35 USC 103(a) as being obviated by Stiene in view of U.S. Patent No. 6,013,164 to Paul.

Applicant respectfully submits that the claims submitted herewith all define subject matter patentably distinguished over the references cited by the Examiner.

As mentioned above, the claims of the present application are directed to an injector pump with separate injector fluid and sample fluid flow paths, an initially closed, integral injector fluid or priming fluid reservoir and a valve for selectively releasing the injector fluid from the reservoir, subject matter not at all disclosed in Stiene. Moreover, Paul also fails to disclose an injector pump with the particular features defined in the amended claims. Therefore, applicant respectfully submits that even the combined teachings of Stiene and Paul would not lead the art skilled person to the injector pump as defined in the claims submitted herewith.

Claims 10 and 15 have been amended to clearly stipulate that the reagent is part of the initially dry micro-porous material of the pump, which materials forms the injector fluid flow path structure. Thus, claims 10-11 and 15-16 now properly define the structure of the apparatus and do not relate to the process carried out with the apparatus. Moreover, applicants respectfully submit that neither Stiene nor Paul disclose any injector fluid flow path made of micro-porous material admixed with a dry reagent mobilizable upon wetup of the micro-porous material. Neither Steine nor Paul teach separate and distinct injector fluid and sample fluid flow paths. The cited art does not even acknowledge any of the advantages achieved and problems addressed with the injector pump structure of the invention which includes separate and distinct injector fluid and sample fluid flow paths. Thus, the prior art fails to teach an injector fluid path as claimed and clearly fails to teach an injector fluid path

separate from the sample fluid path and including the dry reagent. There is no indication whatsoever in the art that it would be advantageous to include the reagents in the injector fluid path rather than the sample fluid path. Thus, the cited references cannot render obvious the subject matter of the amended claims 10 and 15. Withdrawal of the Examiner's rejection under USC 35 §103(a) is respectfully requested.

The Examiner has rejected claims 17 and 18 under 35 USC 103(a) as being obviated by Stiene in view of Paul. It is the Examiner's position that it would have been obvious to the ordinary skilled person to provide an integral fluid reservoir. Applicant respectfully disagrees and refers to the above discussion of the features distinguishing the injector pump of the invention from the teachings of Stiene. Stiene teaches a device used solely for sample fluid (blood) collection and analysis. There is no need in the device of Stiene for any reservoir. More importantly, if a reservoir were included, it would still only be a sample fluid reservoir, not an injector fluid reservoir. Moreover, incorporating a sample fluid reservoir into the apparatus of Stiene would neither maximize the efficiency of the device, nor would the resulting apparatus have any structural or functional resemblance to the pump defined in the claims as presently amended. This deficiency can also not be overcome on the basis of the teachings of Paul. Therefore, applicant respectfully submits that even the combined teachings of Stiene and Paul would not lead the art skilled person to the injector pump structures of the present invention. Withdrawal of the Examiner's rejection of claims 17-18 under USC 35 §103(a) is respectfully requested.

The Examiner's rejection of claims 19 and 20 under 35 USC 103(a) as being obviated by Stiene in view of Paul is respectfully traversed. It is the Examiner's position that it would have been obvious to the art skilled person to use a micro-porous fluidic path having pores of less than 0.2 micrometer radius to obtain the analyte of interest. Applicants respectfully point out to the Examiner that the use of a specific pore size has no relationship to any analyte to be obtained nor any analysis to be carried out, since the micro-porous fluidic path is solely used for the injector fluid, which does not include any analytes, nor is it subjected to any analysis. In fact, the injector fluid has a known composition and electrolyte concentration and the pore size of the injector fluid path is unimportant for any analysis to be carried out on the sample fluid. Analysis is carried out solely on the sample, which is never contained in the injector fluid path.

Thus, the selection of the claimed pore size is not obvious to the person skilled in the art and withdrawal of the Examiner's rejection under USC 35 §103(a) is respectfully requested.

Claims 22 and 23 stand rejected under 35 USC 103(a) as being obviated by Stiene in view of Paul. It is the Examiner's position that it would have been obvious to the ordinary skilled person to provide a fluidic path which is trapezoidal shaped with an application end wider than the effluent end, to achieve the predictable results of better flow control through the device. Applicant respectfully disagrees and points out that the trapezoidal shape is not used for improved flow control. Since the injector fluid is simply an electrolyte solution in most cases, flow control is not an issue. In contrast, the narrowing of the injector fluid path towards the effluent end is used for improved output pressure at the effluent end. Thus, shaping the injector fluid path as claimed would not be obvious to the art skilled person and withdrawal of the Examiner's rejection under USC 35 §103(a) is respectfully requested.

Conclusion

Applicant respectfully submits that the amended independent claims 1 and 3 submitted herewith and all claims dependent therefrom now define subject matter patentably distinguished over the references cited by the Examiner.

Applicant submits that the application is now in condition for further examination and awaits further action.

The Commissioner is hereby authorized to charge any additional fees, and credit any over payments to Deposit Account No. 501593, in the name of Borden Ladner Gervais LLP.

Respectfully

LAUKS, Imants et al.

/Shin Hung/
By: _____
Shin Hung
Reg. No. 55,497
Borden Ladner Gervais LLP
World Exchange Plaza
100 Queen Street, Suite 1100
Ottawa, ON K1P 1J9
CANADA
Tel:(613) 237-5160
Fax:(613) 787-3558
E-mail: ipinfo@blgcanada.com